

b.) Remarks

Claims 17 and 18 have been rewritten in independent format and claims 1-5, 7-12 and 14 are cancelled in order to reduce the issues. Claim 15 is amended to recite the present invention with the specificity required by statute and claims 6, 19 and 20 are amended to maintain their dependency or antecedent basis. Lastly, new claims 21 and 22 are presented in order to more specifically recite various preferred embodiments of the present invention.

The subject matter of the amendment to claims 15 and 21 is found in the specification as filed in Test Examples 1 and 2 at pages 42-45. Accordingly, no new matter has been added.

Claim 14 is objected to under 35 C.F.R. §1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim since the Examiner appears to consider that the syndromes listed are broader than fibromyalgia. In this regard, Applicants respectfully disagree with how the Examiner is reading the claim (as understood, by “including patients who didn’t have fibromyalgia syndrome but still have the further limited disorder”) in view of the plain language of claim 14 (“wherein the fibromyalgia syndrome is selected from the group of consisting of”). Nonetheless, solely in order to reduce the issues, claim 14 has been cancelled.

Claims 12 and 14 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As noted, these claims have above been cancelled.

Claims 12, 14 and 15 are rejected under 35 U.S.C. §112, first paragraph, because the term “‘prophylactic’ agent suggests that treatment includes prevention.” Again, as noted, claims 12 and 14 have been cancelled. As to claim 15, “preventing and/or” has been deleted, as kindly suggested by the Examiner..

Claims 12, 14 and 15 are rejected under 35 U.S.C. §103(a) as being obvious over Suzuki (U.S. Patent No. 5,587,378) in view of Ledent (“Aggressiveness, hypoalgesia and high blood pressure in mice lacking the adenosine A<sub>2a</sub> receptor”, *Nature*, Vol. 388 (1997) 674-78). Suzuki shows Applicant’s formula (1) in claim 11 but does not teach use of the compound for treating fibromyalgia. Ledent is cited as showing that “A<sub>2A</sub> receptor agonists” [sic, antagonists] are known for treating pain. Therefore, the Examiner contends it would have been obvious to utilize Suzuki’s A<sub>2A</sub> receptor antagonist to treat fibromyalgia in view of Ledent.

As to that, last paragraph of Ledent at page 677, left column, reads

“The A<sub>2a</sub> receptor is a target for drug design: antagonists have been considered as treatments for Parkinson’s disease, stroke, pain and inflammatory disorders.”  
(Emphasis added.)

However, Ledent provides no evidence whatsoever to show that adenosine A<sub>2A</sub> receptor antagonists are in fact useful for treating pain. Moreover, as additionally pointed out by the Examiner, Ledent further teaches

“But owing to a lack of selective drugs for different classes of adenosine receptors, several functions mediated by adenosine cannot be attributed to a specific receptor type.” (Emphasis added.)

Thus, the prior art does not teach or suggest to which receptor subtype pain is attributed. In this regard, contrary to the Examiner's argument, the literature reports that pain is attributed to adenosine A<sub>1</sub> receptors (see for instance, Jacobson et al., Adenosine receptors as therapeutic agents, *Nature Review*, Vol. 5 (2006) 247-64, especially, the third paragraph of the right column at page 256 and Figure 7 at page 260)<sup>1</sup>.

In any event, as is well-understood and as shown in the present application, many highly disparate types of compounds are known to be adenosine A<sub>2A</sub> receptor antagonists. Therefore, it is not at all obvious from Ledent to arbitrarily select the particular compounds encompassed by any of claims 17 or 18, let alone the specific compounds recited in claims 15 and 21. Nor, indeed, is any reason to select these specific compounds in order to treat the particular pain disorders recited in claims 15, 17, 18 or 21, which too are not taught by any of the prior art.

Claims 12, 14 and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,587,378 in view of Ledent. By the foregoing amendment, this rejection should now be overcome as well.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 6, 15 and 17-22 remain presented for continued prosecution.

---

<sup>1</sup> This reference and others are provided for the Examiner's review in the accompanying Information Disclosure Statement.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Lawrence S. Perry/  
Lawrence S. Perry  
Attorney for Applicants  
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO  
1290 Avenue of the Americas  
New York, New York 10104-3800  
Facsimile: (212) 218-2200

LSP\ac

FCHS\_WS 4426596\_1.DOC